



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 721

[EPA-HQ-OPPT-2012-0864; FRL-9392-4]

RIN 2070-AB27

### Modification of Significant New Uses of Ethaneperoxoic Acid, 1,1-Dimethylpropyl Ester

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** Under the Toxic Substances Control Act (TSCA), EPA is finalizing an amendment to the significant new use rule (SNUR) for the chemical substance identified as ethaneperoxoic acid, 1,1-dimethylpropyl ester, which was the subject of premanufacture notice (PMN) P-85-680. This action requires persons who intend to manufacture or process the chemical substance for a use that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity. EPA believes that this action is necessary because new uses of the chemical substance may be hazardous to human health. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary, to prohibit or limit that activity before it occurs.

**DATES:** This final rule is effective *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2012-0864, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental

Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:*

Jim Alwood, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8974; email address: [alwood.jim@epa.gov](mailto:alwood.jim@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Does this Action Apply to Me?**

You may be potentially affected by this action if you manufacture, process, or use the chemical substance identified as ethaneperoxoic acid, 1,1-dimethylpropyl ester, (PMN P-85-680). Potentially affected entities may include, but are not limited to:

Manufacturers or processors of the subject chemical substance (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not

listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in § 721.5. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Chemical importers are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements promulgated at 19 CFR 12.118 through 12.127, and 19 CFR 127.28. Chemical importers must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA. Importers of chemicals subject to a SNUR must certify their compliance with the SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export the chemical substance that is the subject of a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)) (see § 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

## **II. Background**

### *A. What Action is the Agency Taking?*

EPA is finalizing an amendment to the SNUR for the chemical substance identified as ethaneperoxoic acid, 1,1-dimethylpropyl ester, (PMN P-85-680), codified at

40 CFR 721.3020. This final action requires persons who intend to manufacture or process the chemical substance for an activity that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity.

This rule was proposed in the **Federal Register** issue of January 28, 2013 (78 FR 5761) (FRL-9370-5). EPA received no public comments in response to the proposal. Therefore, the Agency is issuing a final SNUR, as proposed that:

1. Removes the significant new use requirements for protective equipment, hazard communication, and specific uses identified in the consent order.
2. Modifies significant new use requirements for environmental releases by removing notification requirements for disposal and adding notification requirements for water releases above 61 parts per billion (ppb).
3. Revises the recordkeeping requirements to reflect the modified SNUR requirements.

*B. What is the Agency's Authority for Taking this Action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a “significant new use.” EPA must make this determination by rule after considering all relevant factors, including the four bulleted TSCA section 5(a)(2) factors, listed in Unit IV. of this document. Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture or process the chemical substance for that use. Persons who must report are described in § 721.5.

### III. Rationale for the Rule

During review of PMN P-85-680, the chemical substance identified as ethaneperoxoic acid, 1,1-dimethylpropyl ester, EPA concluded that regulation was warranted under TSCA section 5(e), pending the development of information sufficient to make reasoned evaluations of the health or environmental effects of this chemical substance. The basis for such findings is outlined in Unit II. of the proposed rule to amend this SNUR, included in the **Federal Register** issue of January 28, 2013 (78 FR 5761) (“proposed amended rule”), and in the original final rule **Federal Register** document of June 26, 1990 (55 FR 26102). Based on these findings, a TSCA section 5(e) consent order requiring the use of hazard communication and appropriate exposure, use, and disposal controls was negotiated with the PMN submitter. The SNUR provisions for this chemical substance were consistent with the provisions of the original TSCA section 5(e) consent order. The SNUR was promulgated pursuant to § 721.160, and codified at § 721.1560 and redesignated as § 721.3020.

After the review of new test data subsequent to issuance of the TSCA section 5(e) consent order for P-85-680 and associated SNUR (see Unit II. of the proposed amended rule), and consideration of the factors included in TSCA section 5(a)(2) (see Unit IV.), EPA determined that the chemical substance meets one or more of the concern criteria in § 721.170(b), but that these criteria are no longer met for the personal protective equipment, hazard communication, and specific use notification requirements. Consequently, EPA is proposing this modification to the SNUR at § 721.3020 according to procedures in §§ 721.160 and 721.185.

#### **IV. Significant New Use Determination**

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new use must be made after consideration of all relevant factors, including:

- The projected volume of manufacturing and processing of a chemical substance.
- The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
- The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
- The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors. To determine what would constitute a significant new use for the chemical substance identified as ethaneperoxoic acid, 1,1-dimethylpropyl ester, (PMN P-85-680), EPA considered relevant information about the toxicity of the chemical substance, likely human exposures, and environmental releases associated with possible uses, taking into consideration the four bulleted TSCA section 5(a)(2) factors listed in this unit.

#### **V. Applicability of the Significant New Use Designation**

If uses begun after the proposed rule was published were considered ongoing rather than new, any person could defeat the SNUR by initiating the significant new use before the final rule was issued. Therefore, EPA has designated the date of publication of the proposed rule as the cutoff date for determining whether the new use is ongoing.

Consult the **Federal Register** document of April 24, 1990 (55 FR 17376) for a more detailed discussion of the cutoff date for ongoing uses.

Any person who began commercial manufacture or processing of the chemical substance identified as ethaneperoxoic acid, 1,1-dimethylpropyl ester, (PMN P-85-680), for any of the significant new uses designated in the proposed SNUR modification after the date of publication of the proposed SNUR, must stop that activity before the effective date of the final rule. Persons who ceased those activities will have to first comply with all applicable SNUR notification requirements and wait until the notice review period, including any extensions, expires, before engaging in any activities designated as significant new uses. If a person were to meet the conditions of advance compliance under § 721.45(h), the person would be considered to have met the requirements of the final SNUR for those activities.

## **VI. Test Data and Other Information**

EPA recognizes that TSCA section 5 does not require the development of any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)).
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a TSCA section 4 test rule or a TSCA section 5(b)(4) listing covering the chemical substance, persons are required only to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (see § 720.50). However, upon review of PMNs and SNUNs, the Agency has the

authority to require appropriate testing. In this case, EPA recommends persons, before performing any testing, to consult with the Agency pertaining to protocol selection.

The recommended testing specified in Unit II.A. of the proposed rule may not be the only means of addressing the potential risks of the chemical substance. However, SNUNs submitted without any test data may increase the likelihood that EPA will take action under TSCA section 5(e), particularly if satisfactory test results have not been obtained from a prior PMN or SNUN submitter. EPA recommends that potential SNUN submitters contact EPA early enough so that they will be able to conduct the appropriate tests.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs which provide detailed information on the following:

- Human exposure and environmental release that may result from the significant new use of the chemical substances.
- Potential benefits of the chemical substances.
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

## **VII. SNUN Submissions**

According to § 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in § 720.50. SNUNs must be on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in §§ 721.25 and



720.40. E-PMN software is available electronically at

<http://www.epa.gov/opptintr/newchems>.

### **VIII. Economic Analysis**

EPA evaluated the potential costs of establishing SNUN requirements for potential manufacturers and processors of the chemical substance during the development of the direct final rule. The Agency's complete Economic Analysis is available in the docket under docket ID number EPA-HQ-OPPT-2012-0864.

### **IX. Statutory and Executive Order Reviews**

#### *A. Executive Order 12866*

This action modifies a SNUR for a chemical substance that is the subject of a PMN and TSCA section 5(e) consent order. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993).

#### *B. Paperwork Reduction Act*

According to the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, an Agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument or form, if applicable. EPA has amended the table in 40 CFR part 9 to list the OMB approval number for the information collection requirements contained in this rule. This listing of the OMB control numbers and their subsequent codification in the CFR

satisfies the display requirements of PRA and OMB's implementing regulations at 5 CFR part 1320.

The information collection requirements related to this action have already been approved by OMB pursuant to PRA under OMB control number 2070-0012 (EPA ICR No. 574). This action does not impose any burden requiring additional OMB approval. If an entity were to submit a SNUN to the Agency, the annual burden is estimated to average between 30 and 170 hours per response. This burden estimate includes the time needed to review instructions, search existing data sources, gather and maintain the data needed, and complete, review, and submit the required SNUN.

Send any comments about the accuracy of the burden estimate, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques, to the Director, Collection Strategies Division, Office of Environmental Information (2822T), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001. Please remember to include the OMB control number in any correspondence, but do not submit any completed forms to this address.

### *C. Regulatory Flexibility Act*

On February 18, 2012, EPA certified pursuant to section 605(b) of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), that promulgation of a SNUR does not have a significant economic impact on a substantial number of small entities where the following are true:

1. A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

2. The SNUN submitted by any small entity would not cost significantly more than \$8,300.

A copy of that certification is available in the docket for this rule.

This rule is within the scope of the February 18, 2012 certification. Based on the Economic Analysis discussed in Unit VIII. and EPA's experience promulgating SNURs (discussed in the certification), EPA believes that the following are true:

- A significant number of SNUNs would not be submitted by small entities in response to the SNUR.

- Submission of the SNUN would not cost any small entity significantly more than \$8,300. Therefore, the promulgation of the SNUR would not have a significant economic impact on a substantial number of small entities.

#### *D. Unfunded Mandates Reform Act*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reasons to believe that any State, local, or Tribal government will be impacted by this final rule. As such, EPA has determined that this final rule does not impose any enforceable duty, contain any unfunded mandate, or otherwise have any affect on small governments subject to the requirements of sections 202, 203, 204, or 205 of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

#### *E. Executive Order 13132*

This action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and

responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999).

*F. Executive Order 13175*

This final rule does not have Tribal implications because it is not expected to have substantial direct effects on Indian Tribes. This final rule does not significantly nor uniquely affect the communities of Indian Tribal governments, nor does it involve or impose any requirements that affect Indian Tribes. Accordingly, the requirements of Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000), do not apply to this final rule.

*G. Executive Order 13045*

This action is not subject to Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997), because this is not an economically significant regulatory action as defined by Executive Order 12866, and this action does not address environmental health or safety risks disproportionately affecting children.

*H. Executive Order 13211*

This action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use and because this action is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act*

In addition, since this action does not involve any technical standards, section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note), does not apply to this action.

*J. Executive Order 12898*

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

**X. Congressional Review Act (CRA)**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 721**

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 16, 2013.

Maria J. Doa,

*Director, Chemical Control Division, Office of Pollution Prevention and Toxics.*

Therefore, 40 CFR part 721 is amended as follows:

**PART 721--[AMENDED]**

1. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

2. Amend § 721.3020 as follows:

- a. Revise the section heading.
- b. Revise paragraphs (a)(1) and (a)(2)(i).
- c. Remove and reserve paragraph (a)(2)(ii) and remove paragraphs (a)(2)(iii) and (iv).
- d. Revise paragraph (b)(1).
- e. Remove paragraph (b)(3).

The revisions read as follows:

**§ 721.3020 Ethaneperoxoic acid, 1,1-dimethylpropyl ester.**

(a) *Chemical substance and significant new uses subject to reporting.* (1) The chemical substance identified as ethaneperoxoic acid, 1,1-dimethylpropyl ester (PMN P-

85-680; CAS No. 690-83-5) is subject to reporting under this section for the significant new uses described in paragraph (a)(2) of this section.

(2) \* \* \*

(i) *Release to water*. Requirements as specified in § 721.90 (a)(4), (b)(4), and (c)(4) (N=61).

(ii) [Reserved]

(b) \* \* \*

(1) *Recordkeeping*. Recordkeeping requirements as specified in § 721.125(a), (b), (c), and (k) are applicable to manufacturers and processors of this substance.

\* \* \* \* \*

**[FR Doc. 2013-18180 Filed 07/30/2013 at 8:45 am; Publication Date: 07/31/2013]**